IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSEE WESTERN DIVISION

PATRICIA NOZINICH and PETER NOZINICH,	§	
Plaintiffs,	§	
vs.	§	**Civil Action No.2:09-cv-02105-dkv**
JOHNSON & JOHNSON, INC., and CENTOCOR, INC.,	§	**Jury Demand**
Defendants.	§	

PLAINTIFFS' REPLY TO DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT OR IN THE ALTERNATIVE MOTION TO STRIKE LEARNED INTERMEDIARY DEFENSE

The defendants' response does not raise a material issue of fact for a jury to decide. Therefore, the Court should find that summary judgment is proper because the learned intermediary doctrine does not apply.

I. The plaintiffs' motion for partial summary judgment is based on material, admissible facts.

Specifically, the defendants assert that the plaintiffs have drawn an improper legal conclusion when they asserted that Dr. Ash was not apprised of the information contained in the Periodic Safety Update Reports (PSURs). (D.E. No. 115 p. 8 citing Plaintiff's Statement of Undisputed Material Facts (SUF) ¶¶ 44, 46-47). The defendants assert that the plaintiffs' statement is incorrect because "Data in the PSURs always is reflected in the labeling and in other communications sent to physicians." (D.E. No. 115 p. 8). The defendants are guilty of making the same unsupported legal conclusions that

they accuse the plaintiffs of making. The undisputed, material facts show that on two separate occasions, the defendants provided letters to Dr. Ash regarding the rate of incidence for adverse thrombotic events and neither time did the defendants inform Dr. Ash that they were in possession of the following: an article regarding an association of increased risk of pulmonary embolism with the use of Infliximab (Remicade), a SwissMedic letter requesting comments regarding the 73 cases reported in the article, an internal report entitled "Thromboembotic Events during Treatment with Infiximab (Remicade)," and PSURs numbered 7, 11, and 12. (Plaintiffs' SUF ¶¶ 48–63). All of these post-marketing materials indicated that there is a greater risk of pulmonary embolism/thrombotic events associated with taking Remicade than the .2 percent adverse event rate listed in the defendants' package insert under represents the actual number of adverse events. (Ex. 1 Trew p. 42-23). Furthermore, Dr. Ash testified that she would have been interested in reviewing these materials before making a decision to prescribe Remicade to Ms. Nozinich. (Ex. 2- Ash p. 55). Defendants paternalistic, "we evaluated all the information for you and this is all you need to know" approach towards treating physicians such as Dr. Ash is unacceptable.

Next, the defendants assert that facts related to interactions between Centocor and SwissMedic, the Swiss equivalent of the FDA, are inadmissible under Sixth Circuit law. (D.E. No. 115 at 8). This assertion is wholly unsupported by the citation on which the defendants rely. Meridia Products Liability Litigation v. Abbott Laboratories, 447 F.3d 861, 867 (6th Cir. 2006) court excluded the European label, but made no mention of the interactions between the drug maker and foreign regulatory agencies. Id. Regardless, here, the communications between the defendants and SwissMedic are

admissible because they are offered to show that there were post-market adverse events, which were not reflected in the defendants' label of which the defendants were aware. This was the type of information that Dr. Ash was seeking when she was trying to make a determination of whether she should continue prescribing Remicade to Ms. Nozinich, and Dr. Ash testified she would have taken this information into account. (Ex.2- Ash p. 54). The clear inference is: Defendants did not provide Dr. Ash with complete, honest information either in the package insert or in their responses to her specific inquiries.

Finally, the plaintiffs' allegations dealing with DTC marketing are material facts because they are relevant to the plaintiffs' claims. Ultimately, the decision on whether Ms. Nozinich would take Remicade belonged to her. Her unrefuted testimony is that if the defendants had included a warning for pulmonary embolism in the marketing materials that were designed to persuade her to use the defendants' product, she would not have taken Remicade. (Ex. 3-Nozinich p. 54, 114). For this reason, the defendants assertion that direct to consumer marketing is irrelevant to this case is wrong.

II. Tennessee would recognize direct to consumer (DTC) marketing as an exception to the learned intermediary doctrine.

A. None of the cases cited by the defendants raised the issue of DTC marketing of prescription pharmacetuals or medical devices.

The defendants assert that Tennessee has upheld the learned intermediary doctrine without exception since its adoption in 1994. (D.E. No.115 at 8–10). The defendants' argument that Tennessee courts have continued to apply the learned

intermediary doctrine unabated and without exception is unpersuasive here because none of the cases the defendants rely on presented a factual scenario involving DTC marketing. See e.g., Rodriguez v. Strkyer Corp., No. 2:08-0124, 2011 WL 31416, (M.D. Tenn. Jan. 5, 2011) (no allegation of DTC of pain pump used post surgically); Smith v. Pfizer, Inc., 688 F.Supp.2d 735 (M.D. Tenn. 2010) (did not allege DTC as an exception to learned intermediary doctrine, but did recognize that "a manufacturer of a pharmaceutical has a duty to disclose to physicians and patients material facts about the risks of a drug, particularly when it is engaged in off label marketing uses not prescribed by the FDA."); Isbell v. Medtronic Inc., 97 F.Supp.2d 849 (W.D. Tenn. 1998)(no allegation that manufacturer of cardiac pacing system marketed device directly to consumers); Johnson v. Settle, No. M1999-01237-COA-R3-CV, 2001 WL 585093 (Tenn. Ct. App. Oct. 14, 2009)(no allegation of DTC marketing of acetic acid used during plaintiff's colonoscopy where pharmacy involved did not sell directly to consumers); King v. Danek Medical, Inc., 37 S.W.3d 429 (Tenn. Ct. App. 2000)(no allegation of DTC marketing of pedicle screws used in spinal fusion surgeries).

B. The language used by the Pittman Court indicates that the Tennessee courts would recognize DTC marketing as an exception.

The defendants attempt to convince the Court that abrogation of the learned intermediary doctrine in a direct to consumer marketing case is a departure from existing Tennessee law, but the facts of the Nozinich case fit the exceptions to learned intermediary doctrine that the Tennessee Supreme Court described in Pittman v. Upjohn, 890 S.W.2d 425, 430 (Tenn. 1994). The Pittman Court recognized that "where a product is *marketed solely to professionals experienced in using the product*, the

manufacturer may rely on the knowledge that a reasonable professional would apply in using the product." Pittman, 890 S.W.2d at 430 (citing Pavlides v. Galveston Yacht Basin, Inc., 727 F.2d 330, 338 (5th Cir. 1984); Tracy v. Merrell Dow Pharmaceuticals, Inc., 569 N.E.2d 875, 878–79 (1991)). Here, it is clear that Remicade was also marketed to Ms. Nozinich and that the defendants intended for patients to rely on their marketing materials to make the decision to take Remicade. There is abundant evidence that the defendants intended to circumvent professionals by using DTC marketing. Tennessee did not adopt the learned intermediary doctrine so that the defendants could act with impunity to market their products. Tennessee courts did not intend for the learned intermediary doctrine to be used as a "golden shield" for big pharmaceutical companies. See id. The language used by the Pittman court makes it clear that Tennessee would consider DTC as an exception to the learned intermediary doctrine. See id.

III. Under Tennessee law, there is no requirement that the plaintiffs present expert proof on the adequacy of the warnings.

Under Tennessee law, the consumer expectation test determines whether a product is unreasonably dangerous. The consumer expectation test does not require an expert because it is based on the perspective of an ordinary consumer. Jackson v. General Motors Corp., 60 S.W.3d 800, 804 (Tenn. 2001). Notably, the defendants do not cite a single case relying on Tennessee law to support their assertion that expert testimony is required to prove failure to warn using the consumer expectation test. (D.E. No. 115 at 18–20). A successful claim under the consumer expectation test "depend[s] on whether the trier of fact agrees that the plaintiff's expectation of the

ordinary consumer having ordinary knowledge of the product's characteristics." Id. Thus, a product is unreasonably dangerous if its warning is not calculated to call to the attention of a reasonably careful person the nature and extent of the danger involved in using or misusing the product. See Tenn. Code Ann. § 29-28-105; see Jackson, 60 S.W.3d at 804. Here, the defendants failed to warn Ms. Nozinich in the information that they used to market and promote their drug. They also failed to adequately warn Dr. Ash in the information that they provided in response to her specific inquiries about the relationship between Remicade and pulmonary embolism.

A. Ms. Nozinich was not adequately warned of the risks of thrombotic events or pulmonary embolism associated with Remicade.

Ms. Nozinich was not warned about the risks of thrombotic events associated with taking Remicade. Neither the defendants' brochure nor their DVD made mention of the risk of pulmonary embolism. (Ex. 3-Nozinich p. 54). The medication guide, not the package insert, was intended to provide warnings to patients and was referenced in the DVD did not list thrombotic events generally or pulmonary embolism specifically as a risk associated with taking Remicade. (Ex. 4-Medication Guide). Thus, the defendants, who marketed Remicade directly to patients, did not include any warning about pulmonary embolism or thrombotic events. (Id.). Under the consumer expectation test, Ms. Nozinich would have expected to be warned about the increased risk of serious injury or death from thrombembolic events associated with taking Remicade. Accordingly, under Tennessee law, the defendants did not meet their duty to warn. See Jackson, 60 S.W.3d at 804.

B. Dr. Ash was not adequately warned of the level of adverse thrombotic events associated with Remicade.

Assuming arguendo that learned intermediary doctrine does apply and Dr. Ash is the consumer, the warning given to Dr. Ash must be sufficient as determined from her perspective. See Jackson, 60 S.W.3d at 804. Under the consumer-expectation test, there is no requirement for an expert opinion. See id. Here, Dr. Ash's testimony shows that the warning was insufficient. First, on two occasions Dr. Ash felt that the warning regarding pulmonary embolism given in the defendants' package insert was not sufficient to answer her professional questions regarding whether she should prescribe Remicade. To answer her professional questions, Dr. Ash had to contact the defendants for more information. This fact alone demonstrates that the warning was inadequate.

Further, the defendants' responses to her inquiries were also problematic. As previously explained, the defendants' responses to Dr. Ash's inquiries were incomplete and under-represented the rate of incidence for post-marketing adverse events. The defendants continued to assert that the rate of incidence was equal to placebo despite the fact that their post-marketing materials indicated otherwise. (Ex. 1-Trew p. 42-43). The defendants did not provide Dr. Ash with information which was available to them. (Ex. 2- Ash p. 54). Based on these facts, it is clear that even if Dr. Ash is treated as the consumer, the defendants' warnings were inadequate to make her aware of the risk of thrombotic events associated with taking Remicade.

IV. Direct to consumer marketing is relevant to this case because Ms. Nozinich relied on the defendant's marketing materials.

The defendants ignore the DVD and pamphlet that they produced which Ms. Nozinich relied on to make her decision to take Remicade. She testified that had the defendants' marketing materials warned of a risk of pulmonary embolism, she would not have taken Remicade. (Ex. 3-Nozinich p. 114). Accordingly, all of the defendants' direct to consumer marketing materials are relevant to the plaintiffs' claim.

There is no requirement that the plaintiffs show that Dr. Ash relied on the defendants' marketing materials. Rather, the plaintiffs assert that Dr. Ash relied on the defendants' inadequate warnings, which incorrectly represented the rate of incidence for thrombotic events as equal to placebo rate. Dr. Ash's testimony is that she took this information into account when she first prescribed Remicade to Ms. Nozinich and again when she continued to treat Ms. Nozinich with Remicade after she suffered from pulmonary emboli. (Ex. 2- Ash p. 36). Thus, the plaintiffs have demonstrated undisputed facts supporting Dr. Ash's reliance on the defendants' inadequate label and responses to her inquiries. Under Tennessee law, the defendants must answer for their conduct.

V. The SwissMedic inquiry is admissible.

The SwissMedic, which is the Swiss equivalent of the FDA, submitted an inquiry to the defendants regarding a study which showed a greater rate of incidence of pulmonary embolism associated with Remicade than stated in the defendants' label and responses to Dr. Ash's inquiries regarding the rate of pulmonary embolism associated with Remicade. This information is admissible to show that the defendants knew or should have known that the rate of incidence of pulmonary embolism was higher than reflected in the defendants' labeling. See Fed. R. Evid. 401.

The cases on which the defendants rely to assert that the SwissMedic's inquiry is not admissible are distinguishable because they deal with the foreign regulatory responses to information that a drug is unsafe. Here, the plaintiffs are not seeking to admit regulatory responses, but the plaintiffs seek to admit the communications between SwissMedic and the defendants as evidence that the defendants were on notice of these additional adverse events, but did not share this information with Dr. Ash. In Meridia, for example, the Sixth Circuit excluded a drug's European warning label as evidence of the inadequacy of the label used in the United States. Meridia, 447 F.3d at 867. Here, the plaintiffs are not using the SwissMedic's inquiry to compare Remicade's domestic and foreign labels. The district court of Minnesota excluded evidence of foreign regulatory actions, in an action governed by domestic law, as confusing to the jury, when actions were offered to show notice. Baycol Prods. Litig., 532 F.Supp. 2d 1029, 1054 (D. Minn. 2007). In contrast, here, the plaintiffs do not seek the admission of foreign regulatory actions, but rather the SwissMedic's inquiry to show that the defendants had knowledge of significant case reports that showed a greater rate of incidence of pulmonary embolism than listed in their label. The SwissMedic's inquiry is also relevant because the defendants knew about the inquiry when they responded to Dr. Ash's letter, but did not tell her about it. Defendants' response to the report and inquiry is also telling, illustrating the efforts employed by the giant pharmaceutical company to avoid directly answering SwissMedic's inquiry. (See Defendants' Exhibit H).

But, the In re Seroquel Products Liability Litigation, 601 F.Supp. 2d 1313, 1318-19 (M.D. Fla. 2009) opinion recognized the distinction that the plaintiffs make here: the

communications regarding adverse events as compared to the regulatory responses (i.e. labeling changes). Id. The court noted that the "decision does not necessarily preclude Plaintiffs from introducing evidence regarding the *information* the foreign regulators communicated to [the drug maker] regarding the dangers of [the drug]." Id. (emphasis original). As the court explained, "[t]he information the foreign agencies imparted to [the drug maker] regarding the drugs safety *may* be admissible during Plaintiffs' main case on such issues as notice, knowledge and scienter." Id. (emphasis original).

Thus, there is a distinction between admitting the regulatory response and admitting the data that prompted the regulatory response. Here, the plaintiffs seek to admit the SwissMedic's inquiry to the defendants because it shows the increased rate of pulmonary embolism associated with taking Remicade. Under the reasoning in In re Seroquel Products Liability Litigation, the inquiry is relevant and admissible. See id.

CONCLUSION

In this case, the material, undisputed facts show that the learned intermediary doctrine does not apply. Thus, the Court should grant the plaintiffs' motion for partial summary judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that he is attorney of record for the plaintiff and that he has served a true and correct copy of the foregoing pleading, via electronic filing, through the U.S. District Court's ECF System to:

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On this the 23rd day of May, 2011.

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